DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 18, 2015

Jiangxi Sanxin Medtec Co., Ltd
c/o Ms. Diana Hong
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai 200120
China

Re: K142797
Trade/Device Name: I.V. Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: May 13, 2015
Received: May 18, 2015

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142797

Device Name
I.V. Catheter

Indications for Use *(Describe)*

The proposed device, I.V. Catheter, is intended to be inserted in to a patient's vascular system for short term use (no more than 72 hours) to withdraw blood samples or administer fluid intravenously.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 3 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K142797

1. Date of prepare the summary: June 18, 2015

2. Sponsor Identification

Jiangxi Sanxin Medtec Co., Ltd.
No. 999, Fushan Road, Xiaolan Economic Development, Nanchang, Jiangxi, 330200, China

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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: I.V. Catheter
Proposed Device Common Name: Intravascular Catheter

Regulatory Information for I.V. Catheter
Classification Name: Intravascular Catheter;
Classification: II;
Product Code: FOZ;
Regulation Number: CFR 880.5200;
Review Panel: General Hospital;

Intended Use Statement:

The proposed device, I.V. Catheter, is intended to be inserted in to a patient's vascular system for short term use (no more than 72 hours) to withdraw blood samples or administer fluid intravenously.

5. Predicate Device Identification

Predicate Device
510(k) Number: K083429
Product Name: I.V. Catheter for Single Use
Manufacturer: Weihai Jierui Medical Products Co., Ltd.

6. Device Description

The proposed devices, I.V. Catheters, are sterile, single use devices intended to be inserted in to a patient's vascular system for short term use to withdraw blood samples or administer fluid intravenously.

The I.V. Catheter is a closed system, and further available in two combinations of configurations. All of them are sterilized by Ethylene Oxide to achieve a SAL of 10^{-6}, and packed in a sterility maintenance package. The shelf life of the product is three years.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ASTM F88-09, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F 1140-07 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Package for Medical Applications
- ASTM F1929-98(2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ISO 11135-1:2007 Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation and routing control of a sterilization process for medical devices；
- USP <85> Bacterial Endotoxin Limit
- ISO 10993-3:2003, Biological evaluation of medical devices- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- ISO 10993-4:2002 A1:2006, Biological evaluation of medical devices- Part 4: Selection of tests for interactions with blood.
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro Cytotoxicity;
- ISO 10993-6:2007, Biological evaluation of medical devices- Part 6: Tests for local effects after implantation;
- ISO 10993-7:2008, Biological evaluation of medical devices- Part 7: Test of Ethylene Oxide Residues;
- ISO 10993-10:2010, Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization;
- ISO 10993-11:2006, Biological evaluation of medical devices Part 11: Tests for systemic toxicity;
- ASTM F756-08, Standard practice for assessment of hemolytic properties of material;
- ISO 10555-1:1995/AMD.1:1999/AMD.2:2004(E), Sterile, single-use intravascular catheters-Part 1: General requirements;
- ISO10555-5: 1996/AMD.1:1999(E), Sterile, single-use intravascular catheters- Part 5: Over-needle peripheral catheters;
- ISO594-2:1998, Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -Part 2: Lock fittings
- ISO9626:1991/AMD-1:2001, Stainless steel needle tubing for the manufacture of medical devices

8. Substantially Equivalent (SE) Comparison

Table 1 Product Comparison

Item	**Proposed device**	**Predicate Device K083429**
Product Code	FOZ	FOZ
Regulation Number	CFR 880.5200	CFR 880.5200
Intended Use	The proposed device, I.V. Catheter, is intended to be inserted in to a patient's vascular system for short term use (no more than 72 hours) to withdraw blood samples or administer fluid intravenously.	I.V. Catheter for Single Use, including Type I, Type Y and Type Straight, is intended to be inserted in to a patient's vascular system for short term use to withdraw blood samples, administer fluid intravenously or through which to place monitoring equipment such as blood pressure monitors.
Features	Closed System, Radio Detectable, Color Coding, Single Use	Closed System, Radio Detectable, Color Coding, Single Use
Configuration	Catheter tube, Catheter hub, Needle, Needle handle, Flexible tube and Infusion joint	Catheter tube, Catheter hub, Needle, Needle handle, Flexible tube and Infusion joint
Principle of Operation	Manual	Manual
Sterility	EO Sterilized	EO Sterilized
Performance	Comply with: ISO 10555-1:1995/AMD.1:1999/ AMD. 2:2004 ISO10555-5: 1996/AMD.1:1999(E) ISO 9626: 1991/AMD-1:2006 ISO 594-2:1998	Comply with: ISO 10555-1:1995/AMD.1:1999/ AMD. 2:2004 ISO10555-5: 1996/AMD.1:1999(E) ISO 9626: 1991/AMD-1:2006 ISO 594-2:1998
Biocompatibility	Conforms to the requirement of ISO 10993 series Standards	Conforms to the requirement of ISO 10993 series Standards

9. Substantially Equivalent (SE) Conclusion

The propose device has the same intended use with the predicate device, except that the proposed device is not intended for placing monitoring equipment. The proposed device has less indication compared with the propose device, and the indications are provided on the label and user manual, therefore, this difference is not considered to affect the substantially equivalent between the proposed and predicate device.

The features, configurations, principle of operation, sterility of the proposed are the same as those of the predicate device.

In addition, the results of performance tests performed on the proposed device can also demonstrate the proposed device is complied with FDA recognized standards, which the proposed device was also complied with. The results of biocompatibility studies performed on the proposed device demonstrate that the patient materials used in proposed device are biocompatibile.

Based on the comparison above, the proposed device, I.V. Catheter, is determined to be Substantially Equivalent (SE) to the predicate devices, I.V. Catheter for Single Use (K083429).